IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP., PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02326** **MDL 2326** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO THE FOLLOWING CASES:	
All Cases	**Wave 4**

PLAINTIFFS' COMBINED MOTION AND MEMORANDUM OF LAW TO EXCLUDE THE OPINIONS AND TESTIMONY OF STEPHEN H. SPIEGELBERG, PH.D.

Under Federal Rules of Evidence 702, 403, and 104, the Plaintiffs hereby submit this Memorandum of Law in Support of their Motion to Exclude the Opinions and Testimony of Stephen H. Spiegelberg, Ph.D. In support, the Plaintiffs show the Court the following:

I. INTRODUCTION

Defendant Boston Scientific Corporation ("BSC") designated Mr. Stephen H. Spiegelberg, Ph.D. ("Dr. Spiegelberg") under Rule 26 as an expert witness in all Wave 4 cases. *See* BSC R. 26 Desig. & Discl. Expert Witnesses, 2 (Aug. 14, 2018). BSC disclosed the opinions Dr. Spiegelberg intends to proffer here in **four (4)** Rule 26 reports. BSC served three *of the* four reports in prior waves or bellwether cases in this MDL. For Dr. Spiegelberg's opinions disclosed in the three previously served reports, the Plaintiffs hereby adopt and incorporate by reference the following Motions and Memorandums to Exclude the Opinions of Dr. Spiegelberg:

Report Date & Title	Motion & Memorandum	Reply
Feb. 4, 2014: *Supplemental Expert*	Pls.' Mot. Exclude Test. Of Spiegelberg & Mem. Supp., In re Boston Scientific Corp.,	Pls.' Reply Br. Supp. Mot. Exclude Ops. & Test. Of Spiegelberg, In re Boston

Report of Dr. Stephen Spiegelberg [1]	Pelvic Repair Sys. Prods. Liab. Litig., No. 2:12-md-02326 (S.D.W. Va. Jan. 11, 2018), ECF No. 4287.[2]	Scientific Corp., Pelvic Repair Sys. Prods. Liab. Litig., No. 2:12-md-02326 (S.D.W. Va. Feb. 8, 2018), ECF No. 5031.
June 2, 2014: *Supplemental Expert Report of Dr. Stephen Spiegelberg* [3]	Pls.' Mem. Supp. Mot. Exclude Ops. & Test. Of Spiegelberg, Tyree et al. v. Boston Scientific Corp., No. 2:12-cv-08633 (S.D.W. Va. Aug. 1, 2014), ECF No. 216.[4]	N / A
Nov. 21, 2014: *Expert Report of Dr. Stephen Spiegelberg*[5]	Pls.' Mot. Exclude Test. Of Spiegelberg & Mem. Supp., In re Boston Scientific Corp., Pelvic Repair Sys. Prods. Liab. Litig., No. 2:12-md-02326 (S.D.W. Va. Jan. 11, 2018), ECF No. 4287.[6]	Pls.' Reply Br. Supp. Mot. Exclude Ops. & Test. Of Spiegelberg, In re Boston Scientific Corp., Pelvic Repair Sys. Prods. Liab. Litig., No. 2:12-md-02326 (S.D.W. Va. Feb. 8, 2018), ECF No. 5031.

The discussion below addresses Dr. Spiegelberg's new Rule 26 report served for the first time in Wave 4 ("Wave 4 Report"). *See* Exhibit 1, Supplemental Expert Report of Stephen Spiegelberg, at 1-4 (Apr. 11, 2018). Because *Daubert* bars the testimony Dr. Spiegelberg proffers in the Wave 4 Report, this Court should grant the Plaintiffs' motion.

II. OPINIONS IN WAVE 4 REPORT

Dr. Spiegelberg supplemented his general opinions in the BSC MDL with a Rule 26 report dated April 11, 2018. *See* Ex. 1, Wave 4 Report at 1, 4. In the Wave 4 Report, Dr. Spiegelberg opines, BSC "followed regulatory and industry standards in the design and manufacture of its polypropylene mesh devices, including its failure analysis and testing of its devices." *Id.* at 4.

[1] A true and accurate copy of Dr. Spiegelberg's February 2014 report is attached as **Exhibit 2**.
[2] The Plaintiffs did not attach the testing report challenged in the January 2018 motion to that filing, although BSC attached this report to its response.
[3] A true and accurate copy of Dr. Spiegelberg's June 2014 report is attached as **Exhibit 3**.
[4] The Plaintiffs attached the report challenged in the August 2014 motion to that filing (as Exhibit A).
[5] A true and accurate copy of Dr. Spiegelberg's November 2014 report is attached as **Exhibit 4**.
[6] The Plaintiffs attached the report challenged in the January 2018 motion to that filing (as Exhibit 2).

In addition, Dr. Spiegelberg's Wave 4 Report attacks two (2) methods previously employed by some of the Plaintiffs' experts to reach their opinions in this MDL: (1) Dr. Mays and Dr. Sam Gido's protocols for cleaning explanted devices;[7] and (2) Dr. Guelcher, Dr. Dunn, and Dr. Iakovlev's in vitro testing parameters. *Id.* at 1-3. Dr. Spiegelberg selected three (3) studies published since 2016 to lodge his attacks against the Plaintiffs' experts and their methods. *See id.*

Dr. Mays and Dr. Gido's Cleaning Protocols. Although the Plaintiffs designated Dr. Mays as an expert in Wave 4, the Plaintiffs chose not to designate Dr. Gido. In addition, **Dr. Mays did not conduct any testing for his report in Wave 4**, but rather "relied not only on his knowledge and experience, but also on scientific literature, which are sufficiently reliable methods" under *Daubert* for his Wave 4 opinions. *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 670 (S.D.W. Va. 2014) (quoting *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *51-52 (S.D.W. Va. Sept. 29, 2014)).

Dr. Spiegelberg cites *Thames* (2016) to attack the *Imel* (2015) "testing conducted by [a group of scientists, including] Dr. Jimmy Mays and Dr. Sam Gido." *Id.* at 1 (citing Thames et al., *The Myth: In vivo Degradation of Polypropylene-Based Meshes*, 28(2) INT. UROGYNECOL. J. 285-97 (2016)). In *Thames*, Dr. Spiegelberg explains the authors reported "the necessity of properly cleaning the explanted devices of biologic material." *Id.* Because Dr. Mays and Dr. Gido failed to employ the *Thames* protocol, Dr. Spiegelberg concludes the method "rendered the . . . testing results unreliable." *Id.*

Although Dr. Spiegelberg objects to *Imel's* reliability, the experts in the field disagree – these experts peer-reviewed Dr. Mays' cleaning protocols and concluded the *Imel* methodology

[7] BSC retained Dr. Spiegelberg to criticize Dr. Gido's methods even though the Plaintiffs did not designate Dr. Gido as an Expert in Wave 4.

was sufficiently scientific and reliable for publication. *See* Imel et al., *In-Vivo Oxidative Degradation of Polypropylene Pelvic Mesh*, 73 BIOMAT. 131-41 (2015). In contrast to Dr. Mays, experts in the field have not determined that Dr. Spiegelberg's methodology is reliable. In fact, Dr. Spiegelberg states his protocol fell short of the published protocols and supposed standard in *Thames*: "[m]y own testing of explanted [BSC] pelvic meshes utilize[ed] a shorter cleaning protocol [than *Thames*]." *Id.* at 2. Dr. Spiegelberg concludes that *Thames'* cleaning procedures "support [his] opinion that the [BSC] surgical mesh devices do not undergo material oxidative degradation *in vivo*." *Id.* at 3.

Dr. Guelcher, Dr. Dunn, and Dr. Iakovlev's In Vitro Testing. Dr. Spiegelberg cites *Talley* (2017) and *Iakovlev* (2017) to attack Dr. Guelcher, Dr. Dunn, and Dr. Iakovlev's *in vitro* testing of polypropylene. *Id.* at 3 (citing Talley et al., *Oxidation and Degradation of Polypropylene Transvaginal Mesh*, 28(5) J. BIOMATER. SCI. POLYM. ED. 444-58 (2017); Iakovlev et al., *Degradation of Polypropylene In vivo: A Microscopic Analysis of Meshes Explanted from Patients*, 105(2) J. BIOMED. MATER. RES. B. APPL. BIOMATER. 237-48 (2017)). Dr. Spiegelberg claims Dr. Guelcher, Dr. Dunn, and Dr. Iakovlev's *in vitro* testing under the *Talley* protocols lacks clinical relevance. *See id.* Specifically, Dr. Spiegelberg believes the oxidation solutions under *Talley* are incomparable to the *in vivo* environment. *See id.* To illustrate the point, Dr. Spiegelberg cites the inconsistent topological features observed in explanted polypropylene and *Talley*-oxidized polypropylene. *See id.* Although Dr. Spiegelberg observed surface cracking in explanted polypropylene, *Talley* did "no[t] mention . . . surface cracking" and only observed "pitting, shallow craters and peeling flakes" in the *Talley*-oxidized polypropylene samples. *Id.* Dr. Spiegelberg presumes the discrepancy alone disproves oxidative degradation. *See id.* Because cracking was only observed in explanted polypropylene exposed to biologic material,

Dr. Spiegelberg also attributes cracking to a biological cause rather than oxidative degradation. *See id.* Based on these two assumptions, Dr. Spiegelberg concludes *Talley* supports his general opinion that polypropylene cannot degrade *in vivo*. *See id.*

Next, Dr. Spiegelberg attacks the light microscopy used in *Iakovlev* to examine the outside layers of explanted polypropylene mesh, claiming the method "is not reliable or recognized." *Id.* at 3-4. The *Iakovlev* researchers found a layer of degraded polypropylene with cracks on the outside coatings of the explanted mesh samples. *Id.* at 3. While claiming the *Iakovlev* findings resulted from an unreliable method, Dr. Spiegelberg also construes the findings as evidence that "supports [his] opinion that the cracking observed in studies . . . is due to the presence of biological material, and not degraded polypropylene." *Id.* Specifically, Dr. Spiegelberg claims the "surface cracking" observed on the polypropylene explants in *Iakovlev* demonstrates a material that "is actually consistent with residual biologic material." In other words, Dr. Spiegelberg uses the *Iakovlev* findings as evidence that "the presence of biologic material" – and not degradation – causes "the cracking observed in studies of explanted polypropylene mesh." *Id.* Even though Dr. Spiegelberg believes *Iakovlev's* findings resulted from a "no[n-]reliable" method, Dr. Spiegelberg relied on *Iakovlev's* findings to support his supplemental opinions in the Wave 4 Report.

III. STANDARD

The duty rests with Dr. Spiegelberg to proffer expert testimony and "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Under Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness must be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. Courts admit an expert's testimony if the opinions (1)

"will help the trier of fact to understand the evidence or to determine a fact in issue," (2) are "based upon sufficient facts or data," (3) are "the product of reliable principles and methods" and (4) result from a method reliably applied "to the facts of the case." Fed. R. Evid. 702; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); *Daubert*, 509 U.S. at 597.

An expert witness's testimony must also represent "scientific knowledge," which requires opinions to rest upon a foundation that can withstand appropriate validation and provide relevant evidence for the jury's assistance. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). In other words, his testimony must "fit" the case, and there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig*., 2:12-md-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014), *reconsideration denied*, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). "Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. *Eghnayem*, 57 F. Supp. 3d at 670.

IV. ARGUMENT & AUTHORITIES

A. Dr. Spiegelberg Lacks Sufficient Qualifications To Opine On Regulatory Or Industry Standards For Marketing Section 510(k) Medical Devices.

To testify as an expert, a witness must be "qualified . . . by knowledge, skill, experience, training or education" Fed. R. Evid. 702. Surgeons that use medical devices lack the requisite qualifications to opine on regulatory standards for medical devices,[8] medical device design,[9] and

[8] Dr. Ostergard.
[9] Dr. Blaivas

development of medical devices.[10] *Tyree v. Boston Scientific Corp.*, No. 2:12-CV-08633, 2014 WL 5486694, at *36-37, *47 (S.D.W. Va. Oct. 29, 2014); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 705 (S.D.W. Va. 2014).

Here, Dr. Spiegelberg opines, BSC "followed regulatory and industry standards in the design and manufacture of its polypropylene mesh devices, including its failure analysis and testing of its devices." Ex. 1, Wave 4 Report at 4. However, Dr. Spiegelberg's expertise lies within the field of chemical engineering like Dr. Mays – not medical device regulatory compliance like Dr. Pence.

Dr. Spiegelberg has never used any of BSC's products because Dr. Spiegelberg is not a medical doctor. Even assuming Dr. Spiegelberg could use BSC's products, surgeons that use BSC's products lack the requisite qualifications to opine on the design or manufacture of the products. *See Tyree*, 2014 WL 5486694, at *36-37, *47; *Huskey*, 29 F. Supp. 3d at 705. Because the surgeons using BSC's designs cannot satisfy *Daubert's* qualification prong, Dr. Spiegelberg similarly cannot with even less "experience" using the designs. *See* Fed. R. Evid. 702. In his professional "experience," Dr. Spiegelberg has never navigated the design and manufacture of a medical device through the Section 510(k) clearance process. *Id.*

Dr. Spiegelberg failed to provide any evidence to show any "knowledge, . . . training or education" about the regulations or industry standards that govern the development, design, manufacture, and marketing of medical devices. *See* Fed. R. Evid. 702. Dr. Spiegelberg may have knowledge about some biocompatibility testing required to market a medical device. However, Dr. Spiegelberg neglected to specify "knowledge, . . . training or education" about *each* component that comprises the regulatory or industry procedures for designing and manufacturing a medical device for sale in the United States. Hence, Dr. Spiegelberg's

[10] Dr. Spiegelberg

qualifications prohibit testimony on the entire regulatory scheme or standards within the industry for marketing a medical device from start to finish. *See* Fed. R. Evid. 702. The Court should exclude Dr. Spiegelberg's opinions on the regulatory and industry standards for marketing a medical device in the United States.

B. *Daubert* Bars Dr. Spiegelberg's *Ipse Dixit* On Regulatory And Industry Standards.

Under *Daubert's* reliability prong, an expert must provide a "scientific basis" to opine on the regulatory and industry standards applicable to the development, design, and manufacture of medical devices. *Sanchez*, 2014 WL 4851989, at *31. An expert's opinion on the development of a medical device without *any* basis "evidence[s] nothing more than an unsupported personal opinion." *Id.* Regulatory or industry opinions without *any* "authority" or "ascertainable 'standards' to govern the expert's methodology" amount to *ipse dixit* opinions that "fall short of *Daubert's* reliability prong." *Eghnayem*, 57 F. Supp. 3d at 697 (quoting *Sanchez*, 2014 WL 4851989, at *35 (quoting *Daubert*, 509 U.S. at 594)). Under the reliability analysis, *Daubert* excludes regulatory or industry opinions on the development of medical devices that an expert "base[s] on his personal opinion, rather than any reliable basis." *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 631 (S.D.W. Va. 2013), *on reconsideration in part*, (June 14, 2013).

Here, Dr. Spiegelberg opines, BSC "followed regulatory and industry standards in the design and manufacture of its polypropylene mesh devices, including its failure analysis and testing of its devices." Ex. 1, Wave 4 Report at 4. Dr. Spiegelberg's entire analysis, explanation, and basis for his regulatory and industry opinions fall within the single sentence in the preceding quotation from Dr. Spiegelberg's report. *See generally id.* Dr. Spiegelberg neglected to provide any authority, ascertainable standards, or basis for his regulatory and industry opinions in his Wave 4 Report. *See generally id.* Likewise, Dr. Spiegelberg's prior reports lack regulatory and

industry authorities that govern the *entire* process of designing, developing, and marketing medical devices. *See generally* Ex. 2; Ex. 3; Ex. 4. Applying *Daubert*, *Cisson*, *Sanchez*, and *Eghnayem* to this analysis, Dr. Spiegelberg's regulatory and industry opinions without *any* "authority" or "ascertainable 'standards'" amount to *ipse dixit* opinions that "fall short of *Daubert's* reliability prong." *Eghnayem*, 57 F. Supp. 3d at 697 (quoting *Sanchez*, 2014 WL 4851989, at *35 (quoting *Daubert*, 509 U.S. at 594)). Hence, Dr. Spiegelberg's regulatory and industry opinions in the Wave 4 Report "evidence nothing more than an unsupported personal opinion." *Sanchez*, 2014 WL 4851989, at *31. Like in *Daubert*, *Cisson*, *Sanchez*, and *Eghnayem*, Dr. Spiegelberg's *ipse dixit* opinions on the regulatory and industry standards applicable to BSC's devices are inadmissible because the opinions lack not only a scientific basis, but also *any* basis. The Court should exclude Dr. Spiegelberg's regulatory and industry opinions on BSC's devices because *Daubert* forbids the baseless opinions.

C. The Court Must Exclude Dr. Spiegelberg's Testimony On The Wave 4 Report Because The Opinions Resulted From An Unreliable Method.

In this MDL, an expert's opinion is "unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'" *Eghnayem*, 57 F. Supp. 3d at 676 (quoting *In re Rezulin Prods. Liab. Litig.*, 369 F.Supp.2d 398, 425 (S.D.N.Y. 2005)). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.* at 676-77 (quoting *In re Rezulin Prods. Liab. Litig.*, 369 F.Supp.2d at 425).

Here, Dr. Spiegelberg relied on three (3) studies published after 2015 as the bases for his supplemental opinions in the Wave 4 Report. *See* Ex. 1, Wave 4 Report at 1 n.1, 3 n.3, 5. Based on these studies, Dr. Spiegelberg concludes some experts for the Plaintiffs previously employed

two (2) unreliable methods in reaching their opinions. *Id.* at 1-4. As an initial matter, Dr. Spiegelberg's selection of three studies and a recitation of their findings fails to reflect any "ascertainable 'standards'" that governed Dr. Spiegelberg in reaching his opinions in the Wave 4 Report. *Eghnayem*, 57 F. Supp. 3d at 697 (quoting *Sanchez*, 2014 WL 4851989, at *35 (quoting *Daubert*, 509 U.S. at 594)). Without an ascertainable basis, Dr. Spiegelberg's Wave 4 Report "evidence[s] nothing more than an unsupported personal opinion." *Sanchez*, 2014 WL 4851989, at *31. Hence, Dr. Spiegelberg's *ipse dixit* opinions "fall short of *Daubert's* reliability prong." *Eghnayem*, 57 F. Supp. 3d at 697.

Next, by only considering the three (3) studies he selectively chose, Dr. Spiegelberg's method violates *Daubert* for failing to consider contrary literature. For example, Dr. Spiegelberg opines that the cleaning protocol in *Imel* is unreliable because the method falls short of the requirements set forth in *Thames* for reliably cleaning explanted polypropylene mesh. *See* Ex. 1, Wave 4 Report at 1-2. In reaching the opinion, Dr. Spiegelberg failed to consider the *Thompson* (2017) study that criticized the cleaning methodology in the *Thames* study. *See* Thompson et al., *In Vivo Polypropylene Mesh Degradation is Hardly a Myth*, 28(2) INT. UROGYNECOL. J. 333-335 (2017) (lodging a direct criticism to protocol in the *Thames* study, "The myth: in vivo degradation of polypropylene-based meshes"). By explicitly criticizing the *Thames* cleaning protocols, *Thompson* (2017) demonstrates scientific literature that directly refutes Dr. Spiegelberg's opinion about the reliability of the *Thames* methodology. Dr. Spiegelberg neglected to consider, account for, or mention *Thompson* (2017) in his April 2018 Wave 4 Report. *See generally* Ex. 1, Wave 4 Report at 1-4. Because "the relevant scientific literature contains evidence tending to refute [Dr. Spiegelberg]'s theory and [Dr. Spiegelberg] does not acknowledge or account for that evidence, [Dr. Spiegelberg]'s opinion is unreliable." *Eghnayem*,

57 F. Supp. 3d at 676 (quoting *In re Rezulin Prods. Liab. Litig.*, 369 F.Supp.2d at 425). The Court should therefore exclude Dr. Spiegelberg's testimony on the Wave 4 Report because *Daubert* bars the opinions that resulted from his unreliable methods.

D. Dr. Spiegelberg's Wave 4 Report Offers Legal Conclusions On Daubert.

The Fourth Circuit has held that expert testimony that states a legal standard or draws a legal conclusion by applying law to the fact is inadmissible. *United States v. McIver*, 470 F.3d 550, 561-62 (4th Cir. 2006); *see also Stover v. Fingerhut Direct Mktg., Inc.*, No. 5:09-cv-00152, 2010 WL 1507182, at *2 (S.D.W. Va. Mar. 19, 2010). In the Wave 4 Report, Dr. Spiegelberg proffers reliability opinions on two (2) methodologies previously used by the Plaintiffs' experts. *See* Ex. 1, Wave 4 Report at 1-4. Dr. Spiegelberg concludes each method is not reliable. *See id.* at 1, 3. The reliability of an expert's method comprises one component of the "two-part test t[hat] govern[s] the admissibility of expert testimony under Rule 702." *Eghnayem*, 57 F. Supp. 3d at 668 (citing *Daubert*, 509 U.S. at 597). Although Dr. Spiegelberg offers his opinion on whether the Plaintiffs' experts satisfy *Daubert*, the Supreme Court in *Daubert* entrusted the "gatekeeper" role for expert testimony to this Court, not Dr. Spiegelberg. *See Eghnayem*, 57 F. Supp. 3d at 668 (citing *Daubert*, 509 U.S. at 597). Because Dr. Spiegelberg proffers legal conclusions on the *Daubert* analysis in this case, Dr. Spiegelberg's supplemental opinions in his Wave 4 Report are inadmissible. *See United States v. McIver*, 470 F.3d 550, 561-62 (4th Cir. 2006). The Court should exclude Dr. Spiegelberg's legal conclusions in the Wave 4 Report.

V. CONCLUSION & PRAYER

For these reasons, Dr. Spiegelberg's proposed testimony in the Wave 4 Report should be excluded in its entirety.

Dated: October 18, 2018

By: */s/ Clayton A. Clark*

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CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2018, I electronically filed the foregoing Motion to Exclude with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/ *Clayton A. Clark*

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